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EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/721,476

Applicant(s)

JOY ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. Claim 48 is objected to because of the following informalities: The invention claims a digital to analogue converter for converting signals to digital; this is not possible. Examiner believes that Applicant intended to claim an analogue-to-digital converter for this purpose; for the purposes of examination, it will be treated as such. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 48-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has claimed using the systems' sensors to obtain pressure signals proportional to the direction of air flow, positive or

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negative, through the monitored patient's air passages. There is no support for monitoring the direction of air flow at any point in the specification.

5. Claims 49-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims obtaining pressure amplitude data at a particular sampling rate; the specification calls for obtaining pressure data at a particular sampling rate, and then analyzing the amplitude values of the collected data (pages 13-14 of the specification). As such, there is no support in the specification for obtaining pressure *amplitude* data at a particular sampling rate.

Claim Rejections - 35 USC § 103

6. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu (US Patent 6213955) in view of Westbrook (US Patent Application Publication 2002/0165462) and Schmidt (US Patent 6371114).

Regarding claim 48, Karakasoglu discloses a portable data acquisition unit comprising a solid-state pressure sensor configured to measure pressure signals related to patient breathing (elements 71, 71a; column 3, lines 35-45); means for sampling the signals data at a rate of 6-10 kHz (column 6, line 59); a microcontroller (element 101) that receives the pressure signals and determines their associated clock

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times (column 4, lines 24-56); and an interface that is configured to output data from the unit to another device (column 10, lines 24-26).

Westbrook teaches a system for sensing sleep data using a pressure sensor that may be a strain gauge (paragraph [0089]), since it is well-known in the art to use strain gauges to measure pressure.

Schmidt teaches a sleep respiration sensing system comprising a pressure sensor configured to determine when the patient is inhaling or exhaling (column 9, lines 20-59), in order to further utilize and analyze the gathered data.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu with a strain gauge to measure pressure, as taught by Westbrook, since it is well-known in the art to use strain gauges to measure pressure, and made a distinction between positive and negative air flow, as taught by Schmidt, in order to further utilize and analyze the gathered data.

7. Claims 49, 51, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Starr (US Patent 6342040), Norlien (US Patent 5038773) and Shani (US Patent Application Publication 2002/0115935).

Regarding claim 49, Karakasoglu discloses a portable data acquisition unit configured to collect patient information during a sleep session comprising a housing configured to be attached to a patient (element 11); a solid-state pressure sensor that is configured to measure pressure signals collected by a patient interface positioned adjacent the patient's nostrils (figure 1; sensors 71 and 71a, which are housed in

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element 66); a circuit for sampling data at a rate of 6-10 kHz (column 6, line 59), an amplifier that amplifies the pressure signals and an A/D converter that converts the signals to digital signals (step 131 of figure 5; column 6, lines 15-24); a microprocessor that receives the digital signals and determines clock times associated with the digital signals (element 101; column 4, lines 24-56); an interface that is configured to transfer the data to another device (column 10, lines 24-26). Karakasoglu does not disclose the pressure signals being used to determine positive or negative air flow, sampling the amplitude of the pressure signals, or a battery for powering the data acquisition unit.

Starr teaches a device for monitoring respiration using pressure sensors that may be powered by a battery (column 18, lines 12-21 and 44-46), in order to increase the portability of the device.

Norlien teaches a breath analysis system that uses a pressure sensor to obtain data corresponding to positive or negative air flow from a user's breath, and determines the amplitude of the collected pressure data (column 7, lines 35-46), in order to accurately monitor the patient.

Shani teaches sampling the amplitude of a data signal at a user's desired sampling rate (claim 7), in order to obtain accurate amplitude data.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu with a battery, as taught by Starr, for increased portability, and used the system to monitor whether air flow is positive or negative, as taught by Norlien, and determined the amplitude of the pressure

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signals at the given sampling rate, as taught by Norlien and Shani, in order to accurately monitor the patient's breathing.

Regarding claim 51, Karakasoglu further discloses that the microprocessor is a digital signal processor (column 4, line 45) that comprises non-volatile memory (column 9, lines 50-55) including an algorithm that is configured to analyze pressure and time data to identify sleep disordered breathing events (column 8, lines 40-55; column 10, lines 1-10).

Regarding claim 52, Karakasoglu further discloses that the microcontroller is configured to mark identified events to identify them to a user (column 10, lines 1-10).

8. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Starr, Norlien, and Shani, as applied to claims 49, 51, 52 above, and further in view of Scanlon (US Patent 5853005).

Karakasoglu in view of Starr, Norlien, and Shani discloses all the elements of the current invention, as described above, except for part of the system being configured to mount on the patient's arm. Scanlon teaches a respiratory monitoring system wherein the system's housing may be mounted on a patient in any desired location, such as a limb (figures 7, 10, 12, since the device is attached to a strap that may be wrapped around an arm), in order to make it easier to keep the device close to the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu in view of Starr, Norlien, and Shani, and

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configured it such that it could be mounted on an arm using an arm band, as taught by Scanlon, in order to make it easier to keep the device close to the patient.

9. Claims 53-56 are rejected under 35 U.S.C. 103(a) as being obvious over Karakasoglu in view of Norlien and Shani.

Regarding claim 53, Karakasoglu discloses a method of collecting sleep session data from a patient comprising providing to a patient a portable data acquisition unit that is configured to collect pressure data (column 3, lines 35-45; figure 1) at a rate of 6-10 kHz (column 6, line 59); measuring pressure signals as the patient sleeps (column 4, lines 65-67) and recording a time at which each pressure signal is collected (column 4, lines 52-56); downloading pressure and time data from the unit to a computer, and manipulating the downloaded data with the computer (column 10, lines 24-27). Karakasoglu does not disclose the pressure data being pressure amplitude data.

Norlien teaches a breath analysis system that uses a sensor to obtain pressure data and determines the amplitude of the collected pressure data (column 7, lines 35-46), in order to accurately monitor the patient.

Shani teaches sampling the amplitude of a data signal at a user's desired sampling rate (claim 7), in order to obtain accurate amplitude data.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Karakasoglu and used it to collect pressure amplitude data that is sampled at a desired rate, as taught by Norlien and Shani, in order to accurately monitor the patient's breathing.

Regarding claim 54, Karakasoglu further discloses that the unit is configured for wearing by the patient during sleep (column 2, lines 21-26).

Regarding claims 55 and 56, Karakasoglu further discloses analyzing the data to identify sleep disordered breathing events (column 8, lines 40-55; column 10, lines 1-10, 24-26) before the data is downloaded to a computer.

Response to Arguments

10. Applicant's arguments filed 6 August 2007 have been fully considered but they are not persuasive.

Applicant has argued that Karakasoglu's vibration sensors cannot produce waveforms like square waves; Applicant has not claimed using the device's sensors to do so. Applicant argues that Karakasoglu's stated sampling rate, which anticipates the claimed rate, is to be interpreted as half the stated value. The Examiner disagrees, since Karakasoglu does not provide any reason why the stated rate of sampling would not be used; the Applicant merely appears to be interpreting the clearly stated sampling rate in a manner such that it doesn't anticipate the claimed range, without regard to the actual art. Similarly, Applicant's statement that none of the art of record suggests a high frequency sampling rate is not persuasive, because the statement is only valid if Applicant's unmotivated logic of cutting Karakasoglu's clearly stated sampling rate in half is accepted, which it is not.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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